

REMARKS/ARGUMENTS

The following remarks are responsive to the points raised by the Office Action dated June 10, 2008. In view of the following remarks, reconsideration is respectfully requested.

The Pending Claims

Claims 1-5, 8, 11-22, 25, 28-30, 58-63, and 68 are pending of which claims 1-5, 8, 11-22, 25, 28-30, 58, 60-63, and 68 are withdrawn, and claim 59 is under examination.

Claim 59 is amended to describe the invention more clearly. No new matter is added, and support for the amended claim language may be found within the original specification, claims, and drawings. Claim 59 is supported at, for example, paragraphs [0021], [0042], [0081]-[0082], Example 7, and Figure 6.

Statement under 37 C.F.R. § 1.57(f)

According to the Office Action, the statement under 37 C.F.R. § 1.57 (f) filed February 14, 2007 is insufficient to satisfy the requirements set forth in 37 C.F.R. § 1.57(f) because the statement merely states that the material being inserted represents material incorporated by reference, rather than that the material is the material incorporated by reference.

Submitted herewith is a new statement under 37 C.F.R. § 1.57 (f) signed by the practitioner representing the applicants stating that the material being inserted is the material incorporated by reference and that the amendment contains no new matter, thus meeting the requirements of 37 C.F.R. § 1.57 (f).

Objection under 35 U.S.C. § 132(a)

The Office objects to the amendments filed August 8, 2007 and February 14, 2008 under 35 U.S.C. § 132(a) on the grounds that they allegedly introduce new matter into the disclosure. The Office alleges that the requirements for a proper incorporation by reference have not been met because the statement under 37 C.F.R. § 1.57 (f) filed February 14, 2007 merely states that the material being inserted represents material incorporated by reference, rather than that the material is the material incorporated by reference.

As explained above, submitted herewith is a new statement under 37 C.F.R. § 1.57 (f) signed by the practitioner representing the applicants stating that the material being inserted is the material incorporated by reference and that the amendment contains no new matter, thus meeting the requirements of a proper incorporation by reference. Accordingly, the objection to the amendments filed August 8, 2007 and February 14, 2008 under 35 U.S.C. § 132(a) have been overcome.

Objection to the Specification

The Office objects to the specification as failing to provide proper antecedent basis for the claimed subject matter. According to the Office Action, although the amendment to paragraph [0021] to insert SEQ ID NOs after the recitation of the GenBank® accession number might provide proper antecedent basis for claims drawn to polynucleotides encoding such polypeptides, it is not clear where there is support for the language to the claims.

The specification is amended to provide antecedent basis for claim 59. No new matter is added, and support for the amendment to the specification may be found at, e.g., pars. [0021], [0042], [0081]-[0082], Figure 6, and Example 7. It is respectfully submitted that with this amendment to the specification, the objection to the specification has been overcome and should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

Claim 59 is rejected as allegedly failing to comply with the written description requirement on the grounds that the amino acid sequences of SEQ ID NOs: 6 and 8 have not been properly incorporated by reference because the statement under 37 C.F.R. § 1.57 (f) filed February 14, 2007 was insufficient for the reasons set forth above.

As explained above, submitted herewith is a new statement under 37 C.F.R. § 1.57 (f) signed by the practitioner representing the applicants stating that the material being inserted is the material incorporated by reference and that the amendment contains no new matter, thus meeting the requirements of a proper incorporation by reference. Accordingly, the rejection of claim 59 under § 112, first paragraph on this ground has been overcome.

Claim 59 is also rejected as allegedly failing to comply with the written description requirement on the grounds that there is allegedly no disclosure which would reasonably establish a nexus between the subject matter set forth in the instant claims and the method of inducing apoptosis described in Example 7 of the specification

Claim 59 is amended to recite a method of inducing apoptosis of a natural killer (NK) cell comprising contacting the NK cell with a polynucleotide encoding SEQ ID NO: 6 or 8, in an amount effective to induce apoptosis of the NK cell *in vivo*. Support for claim 59 may be found in the specification as filed, e.g., at paragraphs [0021], [0042], [0081]-[0082], Example 7, and Figure 6.

It is respectfully submitted that with this amendment to the claim, the rejection under 35 U.S.C. § 112, first paragraph has been overcome and should be withdrawn.

Rejection under 35 U.S.C. § 101

Claim 59 is rejected under 35 U.S.C. § 101 allegedly on the grounds that the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

As explained in the specification, the claimed method provides a method of treating cancer in a mammal (e.g., page 4, par. [0017]). Specifically, the method of inducing apoptosis of NK cells defined in claim 59 may be used to treat or prevent cancers such as, e.g., NK cell leukemias and NK cell lymphomas. For example, blastic NK cell lymphoma is derived from cells in various stages of differentiation from stem cells to mature NK cells (see, e.g., Yoshimasu et al., *Bone Marrow Transplantation*, 30, 41-44 (2002), submitted herewith (p. 43, left column, first full par.)). In another example, a boy diagnosed with NK cell leukemia had an increase in NK cells (CD3⁻CD56⁺) in the peripheral blood (see, e.g., Ebihara et al., *Bone Marrow Transplantation*, 31, 1169-1171, submitted herewith (p. 1169, right column, last par.)). Because the method of inducing apoptosis of NK cells defined in claim 59 may be used to treat such conditions, it is respectfully submitted that claim 59 has a “real world,” specific, and substantial utility that would provide an immediate benefit to the public.

Rejection under 35 U.S.C. § 112, first paragraph (enablement)

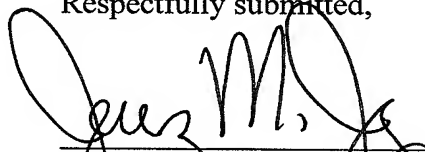
Claim 59 is rejected under § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office alleges that because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth in the rejection under § 101, one of ordinary skill in the art would not know how to use the claimed invention.

For the reasons set forth above, the method defined in claim 59 has a specific and substantial utility in that the claimed method may be used to treat or prevent cancers such as, e.g., NK cell leukemias and NK cell lymphomas. In view of the specific and substantial utility of the claimed method, as well as the guidance, direction, and exemplification set forth in Example 7, claim 59 meets the enablement requirement of § 112, first paragraph.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



Jeremy M. Jay, Reg. No. 33,587
LEYDIG, VOIT & MAYER
700 Thirteenth Street, N.W., Suite 300
Washington, DC 20005-3960
(202) 737-6770 (telephone)
(202) 737-6776 (facsimile)

Date: 10 Sep. 2008

Amendment or ROA - Regular (JMJ/mlg)